Complete Summary

GUIDELINE TITLE

Hereditary breast and ovarian cancer syndrome.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Hereditary breast and ovarian cancer syndrome. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2009 Apr. 10 p. (ACOG practice bulletin; no. 103). [67 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Hereditary breast and ovarian cancer syndrome

GUIDELINE CATEGORY

Counseling
Diagnosis
Management
Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Medical Genetics Obstetrics and Gynecology Oncology

INTENDED USERS

Clinical Laboratory Personnel Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide guidelines for obstetricians and gynecologists in the identification and management of women with hereditary breast and ovarian cancer syndrome

TARGET POPULATION

- Women with greater than an approximate 20-25% chance of having an inherited predisposition to breast cancer and ovarian cancer (recommended for genetic risk assessment)
- Women with greater than an approximate 5-10% chance of having an inherited predisposition to breast cancer and ovarian cancer (genetic risk assessment may be helpful)
- Women with BRCA1 and BRCA2 gene mutations (for risk-reducing surgery)

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Evaluation of patient's risk for hereditary breast and ovarian cancer syndrome
- 2. Genetic counseling
- 3. Genetic testing for BRCA1 and BRCA2 gene mutations
- 4. Risk-reducing salpingo-oophorectomy, with microscopic examination of ovaries and fallopian tubes for occult cancer

MAJOR OUTCOMES CONSIDERED

- Incidence of BRCA1 or BRCA2 gene mutation
- Risk of breast and ovarian cancer syndrome
- Risk of ovarian cancer
- Risk of breast cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1990 and March 2008. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician—gynecologists were used.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort) or case-control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetriciangynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A: Recommendations are based on good and consistent scientific evidence.

Level B: Recommendations are based on limited or inconsistent scientific evidence.

Level C: Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (**I-III**) and levels of recommendation (**A-C**) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Women with *BRCA1* or *BRCA2* mutations should be offered risk-reducing salpingo-oophorectomy by age 40 years or when childbearing is complete.
- For a risk-reducing bilateral salpingo-oophorectomy, all tissue from the ovaries and fallopian tubes should be removed. Thorough visualization of the peritoneal surfaces with pelvic washings should be performed. Complete, serial sectioning of the ovaries and fallopian tubes is necessary, with microscopic examination for occult cancer.
- A genetic risk assessment is recommended for patients with a greater than an approximate 20–25% chance of having an inherited predisposition to breast cancer and ovarian cancer.

Definitions:

Levels of Evidence

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Grades of Recommendations

- **Level A:** Recommendations are based on good and consistent scientific evidence.
- **Level B:** Recommendations are based on limited or inconsistent scientific evidence.
- Level C: Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Screening and prevention strategies can reduce morbidity and mortality from breast cancer and ovarian cancer.
- Clinical genetic testing for gene mutations allows physicians to more precisely identify women who are at substantial risk of breast cancer and ovarian cancer. For these individuals, screening and prevention strategies can be instituted to reduce their risks. Obstetricians and gynecologists play an important role in the identification and management of women with hereditary breast and ovarian cancer syndrome.

POTENTIAL HARMS

Surgical risks

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The information in this guideline is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Apr

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins - Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

ACOG committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 19, 2009. The information was verified by the guideline developer on September 11, 2009.

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